Health Canada Santé Canada

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Media Lines

U.S. FDA revises eligibility criteria for certain filtering facepiece respirators

Issue Statement: On May 7, 2020, the United States Food and Drug Administration (US FDA) reissued the Emergency Use Authorization (EUA) for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China to remove one of the eligibility criteria: the authorization of respirators based on review of test reports from recognized independent test laboratories submitted to the US FDA by the manufacturer or importer. The FDA is taking this regulatory action because a number of these respirators failed to demonstrate a minimum particulate filtration efficiency of 95% in testing conducted at the National Institute for Occupational Safety and Health (NIOSH). Media have reported that this action reduced the number of US FDA-approved KN95 manufacturers from approximately 80 to 14.

A letter to healthcare professionals from the US FDA explained that respirators that were removed from Appendix A of the EUA and that did not meet their labeled performance standard are no longer eligible and are no longer authorized to be marketed or distributed in the US as respirators. The letter clarifies that they may be re-labeled as face masks (rather than respirators) and authorized if certain criteria are met under the Face Mask umbrella EUA. The US decision is expected to impact the supply of face-piece respirators in Canada. It puts into question the quality and effectiveness of certain face-piece respirator products marketed in Canada. Health Canada is taking regulatory action. Media attention is expected.

The US Centers for Disease Control and Prevention (US CDC) has also expressed concerns with some KN95 respirators (specifically those with ear loop design) that pose a difficulty in achieving a proper fit, which is essential for use. N95s use a head band design (not ear loops) and the fit and seal appear easier to achieve.

Key Messages:

- Health Canada understands that health care professionals providing care to Canadians rely on personal protective equipment (PPE) including respirator masks to keep them safe. The quality, effectiveness and safety of health products are always top of mind for Health Canada.

- On May 7, 2020, the US FDA issued revised guidance, indicating that certain filtering facepiece respirators may not provide adequate respiratory protection and issued a letter to health care providers, indicating that certain products currently being sold in the US do not meet expected filtration standards and are no longer authorized to be marketed or distributed in the United States as respirators. They may be re-labeled as face masks and authorized if certain criteria are met.

- Health Canada has contacted companies that may be importing or distributing certain respirators, including KN95 respirators, in Canada that may not meet safety and effectiveness standards to request that they immediately stop sale and notify their customers as well as relabel products to indicate that while these masks may not meet the standards required for frontline healthcare workers, they could be used as face masks in settings where a 95% filtration is not needed. Health Canada will take appropriate action and inform Canadians, as necessary.

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- Provincial and territorial health authorities and healthcare institutions are being asked to review their inventories of KN95 respirators to confirm that they meet the Government of Canada technical specifications for healthcare settings for COVID-19 response.

- This action does not implicate KN95 respirators purchased by the Government of Canada and tested by the Public Health Agency of Canada (PHAC). Before allocating any personal protective equipment to the provinces or territories for frontline healthcare workers, PHAC conducts a quality verification. For KN95 respirators, this includes a visual inspection to check for defects in design and construction, and testing, as supported by the National Research Council, to confirm that they meet filtering specifications.

- KN95 respirators distributed to provinces and territories by PHAC meet the Government of Canada's technical specifications for healthcare settings for COVID-19 response.

- To date, a large majority of the products received by the Government of Canada have met the technical specifications for healthcare settings for COVID-19 response; however, as a result of the Public Health Agency of Canada's stringent review process, approximately 9.9 million KN95 respirators were assessed as not meeting the technical specifications.

- Health Canada will continue to accept equivalent alternate standards to N95, including KN95, but will request evidence of quality manufacturing and validated test results from independent testing facilities before the Department will authorize such products.

Supplementary Key Messages on Work with the US FDA

- Health Canada works closely with other regulators, such as the US FDA, and takes comparable actions when necessary to help ensure the quality, effectiveness and safety of medical devices for the Canadian market.

- Health Canada is actively engaged and urgently responding to the US FDA's change to its Emergency Use Authorization for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China.

- The NIOSH assessment webpage includes a list of KN95 respirators manufactured in China that have been tested and the test results. Health Canada will continue to take action to ensure that products that do not meet the appropriate standards are not imported or distributed in Canada.

Supplementary Messages on Market Authorization of N95 and KN95 respirators and the Interim Order

- There are two ways for companies to sell and import COVID-19 Class I medical devices to the Canadian market. They can apply for a market authorization by Health Canada through the Interim Order for Expedited Access to Medical Devices for COVID-19 pathway or the Medical Device Establishment Licence (MDEL) pathway.

- Health Canada reviews the scientific evidence provided by the manufacturers through the Interim Order pathway to support the safety and effectiveness of devices before issuing authorizations for these devices.

- Current MDEL holders have been advised that they are not permitted to import or distribute respirators that have failed NIOSH testing unless they are re-labelled as face masks. New MDEL applicants will also be responsible for ensuring that they are not importing or distributing respirators that do not meet the required filtration standards.

- N95, KN95 and equivalent respirators are Class I medical devices. However, in order to enable Health Canada to conduct a scientific review in advance of authorizing the sale of these devices, manufacturers are encouraged to submit applications through the Interim Order pathway as opposed to the Medical Device Establishment Licence (MDEL) regulatory pathway.

Supplementary Messages on Testing and Status of KN95 Respirators

- In Canada, manufacturers of Class I medical devices, which include N95 and KN95 respirators, previously have had the option of two regulatory pathways: a medical device establishment licence (MDEL) or an Interim Order (IO) authorization.

- While Health Canada will continue to accept equivalent alternate standards to the NIOSH N95, including KN95 and FFP2, it will now request evidence of quality manufacturing and validated test results. Health Canada may request results from independent testing facilities as a condition of authorization under the Interim Order.

Supplementary Messages for Healthcare Settings

- Health Canada recommends that, although somewhat different than the N95 respirator, healthcare professionals conduct the appropriate face fit testing before using these respirators.

- Health Canada is committed to ensuring that the medical devices available to Canadians meet standards of safety and effectiveness. Health Canada is monitoring potential issues on the Canadian market and will take action as necessary.

Supplementary Messages on Compliance and Enforcement Options

- A number of compliance and enforcement options are available to correct non-compliance or to mitigate a risk to Canadians including on-site visits, recalls, public communications, and product seizures.

- Health Canada takes a risk-based approach that takes into account the circumstances of each case to protect the health and safety of Canadians.

- The primary objective of Health Canada’s compliance and enforcement approach is to manage the risks to Canadians using the most appropriate level of intervention.

- In this case, while some KN95 respirators may not meet the standards required for frontline healthcare workers, they could still be used as face masks in settings where 95% filtration standards are not needed; thus recalling the impacted respirators and relabelling them as masks addresses the risk posed.

Supplementary Messages on Canada’s Supply of PPE and Medical Supplies

- Health care workers need medical masks, including surgical masks, medical procedure masks, and respirators, such as N95 respirators. It is extremely important to maintain the supply of medical masks where it is needed.

- The Government of Canada is working to ensure that health care workers have the PPE and medical supplies they need. We are doing this through collaborative bulk procurement with the provinces and territories, building domestic production capacity, and identifying potential alternatives and ways to extend product life.

- Canada is working to rapidly allocate PPE and medical supplies to the provinces and territories as per an approach agreed upon by federal, provincial and territorial Ministers of Health.

- PPE and medical supplies received by the Government of Canada, whether procured internationally or domestically, are verified by PHAC to ensure they meet Government of Canada technical specifications for healthcare settings for COVID-19 response. It is the same process for donations.

- If PHAC cannot account for the quality of products, they will not be allocated to the provinces and territories for frontline healthcare response.

- The process for verification varies depending on the medical device. For example, KN95 respirators, as an accepted alternative to N95 respirators, are visually inspected to check for defects in design and construction, and tested to confirm they meet specifications for filtering face pieces.

- To date, a large majority of the products received by the Government of Canada have met the technical specifications for healthcare settings for COVID-19 response; however, as a result the Public Health Agency of Canada's stringent review process, approximately 9.9 million KN95 respirators were assessed as not meeting the technical specifications

Questions and Answers:

Q1. With fewer approved N95 respirator manufacturers in the US, what will the impact be on the Canadian supply of N95 respirators?

Health Canada understands that health care professionals providing care to Canadians rely on Personal Protective Equipment including respirator masks to keep them safe. The quality, efficacy and safety of health products are always top of mind for Health Canada.

The Government of Canada will continue to work to secure an adequate supply of N95 and equivalent respirators to meet the needs of the healthcare system. We are doing this through collaborative bulk procurement with the provinces and territories, building domestic production capacity, and identifying potential alternatives and ways to extend product life.

Q2. I am a healthcare professional. What should I do with my KN95? Where should I go to know whether it has been tested and passed the test?

Healthcare professionals can consult the NIOSH assessment webpage to determine whether their KN95 respirators manufactured in China have been tested and to review the testing

results. Respirators that may not meet their labelled performance standard should not be used by frontline healthcare workers to protect themselves from COVID-19.

Respirators distributed to provinces and territories by PHAC meet the Government of Canada technical specifications for healthcare settings for COVID-19 response.

Q3. How is Health Canada adjusting its standards or review process in light of the US FDA's announcement?

Health Canada will invite importers, distributors or manufacturers of N95 and N95 equivalent, including KN95, respirators to submit their COVID-product applications under the Interim Order process.

Health Canada will continue to accept equivalent alternate standards to N95, including KN95, but will request evidence of quality manufacturing and validated test results from independent testing facilities for their authorization.

Q4. What is Health Canada doing to mitigate medical device shortages resulting from COVID-19?

Health Canada is actively monitoring the potential impact of the COVID-19 pandemic on the supply of medical devices in Canada. The Department is taking a three-pronged approach: surveillance, multi-stakeholder collaboration, and efforts to secure supplies of needed health products.

Health Canada continues to actively engage the medical device industry as well as provinces and territories to monitor for any signals of supply disruptions in Canada.

Manufacturers and importers are now required to notify Health Canada of shortages of medical devices considered critical in relation to COVID-19. In addition, manufacturers and importers are encouraged to report shortages of other medical devices on a voluntary basis.

Manufacturers and importers must notify Health Canada within five days of becoming aware of a real or anticipated shortage. This is similar to what is already required of drug companies. Public reporting of shortages helps the health care system prepare for supply disruptions.

Health Canada has contacted all Medical Device Establishment Licence holders and all Medical Device Licence holders in Canada to remind them of the requirement to report any anticipated and actual medical device shortages of critical devices that are on the List of Medical Devices related to COVID-19, which currently includes:

- Masks (e.g. surgical, procedure or medical masks)
- N95 respirators for medical use
- Face shields
- Gowns
- Ventilators (including bi-level positive airway pressure machines)

The Department is also expediting the issuance of Medical Devices Establishment Licences to increase the number of establishments that may import and distribute critically needed medical devices.

The Department will continue to closely monitor this situation and take any necessary action in collaboration with companies, provinces and territories and other stakeholders to help ensure continued supply of medical devices in Canada.

Q5. What do the different letters and numbers in the mask types refer to? What is an N95 vs a KP95 vs a KN95?

N95 and KN95 are considered equivalent designations for respirators that are expected to meet filtration standards of 95 percent.

The letter N stands for non-oil resistant, whereas the letter P indicates that the mask is oil proof. The N95 respirators meet the NIOSH US standard and KP95 and KN95 meet an equivalent Chinese standard.

The Government of Canada has developed detailed specifications for PPE such as disposable N95 respirators. Additional information about the products and services needed along with related specifications is available on Health Canada's website.